DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 27, 2015

Teleflex, Inc.
ARROW International, Inc.
Chet Jones
Regulatory Affairs Specialist
2400 Bernville Rd.
Reading, PA 19605

Re: K140110
Trade/Device Name: ARROW FlexTip Plus Epidural Catheter
Regulation Number: 21 CFR 868.5120
Regulation Name: Anesthesia Conduction Catheter
Regulatory Class: Class II
Product Code: BSO, CAZ
Dated: February 23, 2015
Received: February 24, 2015

Dear Mr. Jones:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith -S

Erin I. Keith, M.S.
Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K140110

Device Name
ARROW® FlexTip Plus® Epidural Catheter

Indications for Use *(Describe)*
The Arrow Epidural Catheter permits access to the epidural space for the administration of epidural anesthetic. The epidural catheter is intended for use up to 72 hours.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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006 BUNDLED TRADITIONAL 510(k) SUMMARY

Submitter Information

Name	ARROW International, Inc. (subsidiary of Teleflex Inc.)
Address	4024 Stirrup Creek Dr., Suite 720 PO Box 12600 Durham, NC 27703
Phone number	919-433-2579
Fax number	919-433-4996
Contact Person	Chet Jones
Date prepared	June 30, 2014 (Revised March 26, 2015)

Trade Name

1. ARROW® FlexTip Plus® Epidural Catheters

Common/Usual Name

1. Epidural Catheter

Classification Name

Catheter:
- BSO – Anesthesia Conduction Catheter
- 21 CFR 868.5120
- Class 2

Kit:
- CAZ – Anesthesia Conduction Kit
- 21 CFR 868.5140
- Class 2

Predicate Device

1. FlexTip Plus Epidural Catheter - K103658

Modification and Changes to Predicate

The purpose of this traditional 510(k) is to update the MR Conditional statements in the Instructions for Use (IFU). The update is based on magnetic resonance testing performed by Shellock R&D Services. The purpose of the update is to make a correction and to align the MR Conditional statements to the current best practices.

The update to the MR Conditional statements in the IFU is the only modification. The devices that are the subject of this submission are identical to their respective predicates in all other respects, including their technological characteristics, materials, indications for use, and FDA classification.

Device Description

ARROW® FlexTip Plus® Epidural Catheters are single lumen catheters featuring a wire re-enforced polyurethane body with centimeter markings to facilitate placement.

Indications for Use

The Arrow Epidural Catheter permits access to the epidural space for the administration of epidural anesthetic. The epidural catheter is intended for use up to 72 hours.

Substantial Equivalence Comparison to Predicates

ARROW FlexTip Plus Epidural Catheters were cleared under K103658. No changes have been made to the catheters or components since receiving clearance. Substantial equivalence between the device subject of this submission and the predicate device is based upon the fact that they are identical in regards to technological characteristics, design, materials, indications for use, and FDA classification.

The only change for these devices is an update to the MR Conditional labeling based on magnetic resonance testing performed by Shellock R&D Services. The details of the update are provided in Section 014 Proposed Labeling. The test report is provided in Attachment C.

Table 1 Substantial Equivalence Comparison to Predicates

Characteristic	Comparison to Predicate
Product Classification	No change
Intended Use	No change
Technological Characteristics	No change
Materials	No change
MR Conditional Labeling	See Table 1 in Section 014 Proposed Labeling.
Performance Testing	Evaluation of Magnetic Field Interactions, Heating and Artifacts for FlexTip Plus Epidural Catheter, 19-gauge x 90-cm, Nonmagnetic SS Version by Shellock R&D Services, 12/09/11, Revised 7/15/2013. *

* The same testing was submitted in support of the MR Conditional statements cleared in the predicate 510(k) K103658. However, the test was found to contain an error and was revised, producing the 7/15/2013 version of the report. This performance testing is presented in support of the MR Conditional statements and is not intended to support substantial equivalence. Substantial equivalence is based upon the devices being identical to their predicates in all respects.

Substantial Equivalence Conclusion

The proposed update to the MR Conditional labeling establishes parameters for the safe use of these catheters in a magnetic resonance environment. It does not impact the safety and effectiveness of ARROW FlexTip Plus Epidural Catheters, and does not raise new questions of safety or efficacy.